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14. ABSTRACT
The RSI Technical Working Group (TWG) developed a recommendation defining the properties and types of significant photothermal retinal lesion injuries that is consistent with the language and intent of DoD Instruction 3200.19.

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Properties and Types of Significant Photothermal Retinal Lesion Injuries

Risk Significant Injury (RSI) Implementation Guidance

RSI Technical Working Group

September 2016

Purpose

The purpose of this RSI Implementation Guidance is to define the properties and types of photothermal retinal lesions that should be used to classify injuries as significant or not significant. Although probably most relevant for non-lethal dazzling laser weapons, the types, properties, and classification of significance of photothermal retinal lesions described in this document are relevant to all non-lethal weapon (NLW) systems capable of causing these types of injuries. Lasers and other light emitting devices may be capable of creating other types of retinal injuries to include photochemical and photomechanical retinal lesions. However, the scope of paper is limited to retinal lesions produced from a photothermal interaction between the light and the retinal tissue. Based on need, e.g. the identification of NLW systems with photochemical or photomechanical injury risk, additional RSI guidance will be published.

In previous developmental efforts involving dazzling lasers, the ANSI[1] Maximum Permissible Exposure (MPE) for visible lasers, a safety standard effectively representing zero risk of any retinal injury, was used as a surrogate metric for RSI. As will be shown, this Implementation Guidance while still being conservative can be used to replace this MPE deterministic safety standard allowing for a more realistic probabilistic significant injury assessment, which could widen the available trade space for future dazzling laser development.

Being overly conservative with an RSI estimation can add cost, schedule, and performance risks to a system development program. The intent of this work is to provide an RSI estimation framework that is as accurate as possible given the available data. However, when definitive data sets are lacking, erring on the side that most people would agree is a conservative estimate for RSI allows for the establishment of methodologies and models that can make verifiable, valid, and quantifiable statements such as 'the RSI of this system does not exceed X%'.

Background

DoD policy (DoDD 3000.03E) states that NLWs are "developed and used with the intent to minimize the probability of producing fatalities, significant or permanent injuries, or undesired damage to materiel, but do not, and are not intended to, eliminate risk of those actions entirely." While NLWs are intended to produce reversible effects, reversibility is not required. The RSI for any given weapon shall be identified by the combat developer to assist in materiel development and enable force commanders to understand the potential risks associated with the use of specific NLWs. Characterization of the human effects resulting from NLW use shall be conducted during the materiel development process to assess the likelihood of achieving the desired effect(s) and to identify the RSI for counter-personnel systems, as well as the RSI for collateral damage to humans from counter-materiel systems.

RSI is a metric intended to evaluate the risk of a NLW (when functioning properly and employed as intended) causing permanent injury. RSI is associated with the acceptable yet still unintended level of non-reversibility for counter-personnel systems. For example, if a particular non-lethal weapon, device,

[1] American National Standards Institute (ANSI)

or munition is assigned an RSI of 10%, then there is a 10% probability that the target may sustain a permanent injury preventing the target from returning to his or her pre-engagement functionality.

Non-reversibility, applied to humans, is fundamentally a measure of permanent injury[2] that is defined in terms of the physical damage which restricts the employment or other activities of the person for the rest of his or her life. Many injuries can be successfully treated with medical care either by preventing permanently disabling outcomes from occurring, i.e. treating complications caused by the injury, or by mitigating the impact of permanently damaged tissue or structures.[3] Therefore, the probability that an injury caused by a NLW will result in a permanently (i.e. non-reversible) disabling outcome depends on the level of medical treatment assumed.[4] DoDI 3200.19[5] states that injuries that cannot be treated with limited first responder care, presumably to prevent a permanently disabling outcome, are considered 'significant'. In other words, RSI is the likelihood (i.e. probability) that a NLW system will cause a permanent injury (physical damage to a person that permanently impairs physiological function and restricts the employment or other activities of that person for the rest of his or her life) assuming only limited first responder level of treatment (self-aid, buddy-aid, combat lifesaver skills).

Rather than being strictly prescriptive, RSI Implementation Guidance documents, like this one, are intended to provide the DoD NLW community with relevant, peer-reviewed, RSI-focused human effects analysis to incorporate into developmental NLW efforts. These documents are consistent with the policy guidance in DoDI 3200.19 and can be assumed to represent a 'best practice' for the particular topic covered. This RSI Implementation Guidance draws heavily from the conclusion of a literature review and analysis report, commissioned by the Joint Non-Lethal Weapons Directorate, which was completed in December 2015 by the Institute for Defense Analyses. Additional technical details and justifications for particular assumptions can be found in that document.[6]

Probability of Significant Injury Given it Occurred, P(SI|IO)

RSI can be written as the product of two separate conditional probabilities,

Eq. (1) $$RSI = P(IO) * P(SI|IO)$$

where $P(IO)$ is the probability that an injury will occur and $P(SI|IO)$is the probability that the injury is significant given that it occurred. The focus of this Implementation Guidance is on estimating the $P(SI|IO)$ portion of the RSI equation. However, the available data are limited and relevant data sets are not easily developed via experimentation; therefore, assumptions must be made. In all cases where assumptions are made for this Implementation Guidance, the more conservative estimate is used (in this case meaning to err in the direction of estimating more injuries than will actually occur), i.e.

Eq. (2) $$P(SI|IO)_{estimated} > P(SI|IO)_{actual}$$

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[2] Injuries that result in death represent the extreme end of "permanent injury" but nonetheless, death as an outcome fits entirely within the definition of permanent injury. That is, injuries that result in death are considered permanent injuries.

[3] Examples of treatment that mitigates the impact of rather than preventing a permanent injury include hearing aids, prosthetics, and/or corrective surgical interventions.

[4] Although true in general, there are no medical treatments that mitigate the permanent impact of retinal lesions.

[5] DoD Instruction 3200.19, "Non-Lethal Weapons (NLW) Human Effects Characterization," May 17, 2012

[6] Hirsch et al. "Significance of Retinal Lesions Potentially Caused by Dazzling Lasers," IDA Document D-5691, Institute for Defense Analyses, December 2015

The Significance of Retinal Lesions

Photothermal retinal lesions occur when incident light is sufficient to heat retinal tissue to a point where tissue proteins are denatured or coagulated and lose function. Though retinal lesions may be permanent in the sense that the damaged retinal tissue may never regenerate, it may not always result in a life-long disabling injury, and therefore, it would not always be considered a significant injury. Retinal lesions can cause scotomas, which are areas within a person's visual field where the vision is absent or deficient. Retinal injuries caused from NLW exposures should be considered significant, in the sense of being permanently disabling in line with DoDI 3200.19, when a resulting scotoma causes:

1) Visual acuity worse than 20/40 [7,8]
2) Permanent visual field impairment such that the average visual field is 60°or less, or if a scotoma takes up 25% or more of the visual field, or if a scotoma is centrally located (i.e. within the macula, no more than 2.75 mm from the center of the foveola).[9]

As discussed in Hirsch et al., injuries that still leave the person with visual acuity better than or equal to 20/40, e.g. 20/20 which is considered normal vision, would not result in permanent disabilities that restrict "the employment or other activities of that person for the rest of his or her life."[10] The same is true, also discussed in Hirsch et al., for injuries where the person is left with an average field of vision greater than 60°. For reference, Hirsch et al. states that each eye "can see 60° nasally (toward the nose), 100° temporally (away from the nose), 75° inferiorly (down), and 60° (superiorly)." For binocular vision, this corresponds to nearly 180° field of view in the horizontal direction (90° left and right) and 135° vertically.

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[7] This refers to the visual acuity given an injury and only Limited First Responder Care (LFRC) treatment. We assume all available vision correction treatment is beyond LFRC. So this would, by circumstance, refer to uncorrected vision. However, theoretically if there were a LFRC treatment that did provide adequate vision correction, then it would only be significant if the vision could not be corrected to 20/40.

[8] This implicitly assumes everyone engaged has normal vision, which, of course, is a conservative assumption. If a person's vision is worse than 20/40 to begin with, then a photothermal retinal lesion will not prevent them from returning to their pre-engagement level of function. Making the assumption that everyone targeted has better than 20/40 visual acuity will lead to false-positive results in some cases (that is, incorrectly attributing a disabling NLW injury to a person). However, the expected rate of false-positives is quite low for the following reasons.
First, a centrally located retinal lesion is not as easily correctable as refractive visual acuity errors (e.g. corrective lenses). Many people with a visual acuity worse than 20/40 (uncorrected) have conditions that are correctable and already have corrective lenses (the proportion of which will vary by region/population). However, if they receive a centrally located photothermal retinal lesion, they will now have an uncorrectable, disabling condition (even if they already had corrective lenses). The assumption that everyone has better than 20/40 vision only causes an over estimation of the rate of disabling outcomes for people who have both worse visual acuity and either do not have corrective lenses or have an uncorrectable condition.
Second, the visual acuity loss due to a centrally located photothermal retinal lesion will always occur along with a loss of the visual field, which itself is disabling. A false-positive will only happen when the person has pre-existing uncorrected visual acuity worse than 20/40 and also a pre-existing disabling field of vision loss.
Third, the number of individuals that would result in a false positive retinal lesion RSI-event would likely be much smaller in the target population than the general population because we can assume that already visually disabled individuals would be less likely to engage as often in activities where NLW would be used.

[9] Idem, Hirsch et al.

[10] Idem, DoD Instruction 3200.19, quote from the definition of permanent injury

The significance of retinal lesions is dependent on both the severity and location of the injury.

Severity: Medical Categorization of Retinal Lesions

In the medical and scientific literature, photothermal lesions are often categorized as subthreshold, threshold, or suprathreshold. Threshold lesions are lesions that can be detected by traditional ophthalmological or fundus photography methods, whereas subthreshold lesions may only be detected by more advanced detection methods. Threshold retinal lesions are defined as minimally visual lesions (MVL) and are approximately 25 μm in diameter. Suprathreshold lesions, which like threshold lesions can be detected by traditional ophthalmological methods, are lesions associated with more severe retinal damage and secondary effects such as preretinal, intraretinal, and vitreoretinal hemorrhage, macular holes, and neovascularization.

Photothermal retinal lesions are considered significant when they are associated with complications such as hemorrhage, macular holes, retinal proliferation, and neovascularization that require medical treatment beyond what could be provided by limited first responder care in order to prevent the permanently disabling outcomes listed above. These additional complications are only associated with suprathreshold lesions; and even though they do not always lead to permanently disabling outcomes, in the absence of a definitive data set, we assume that suprathreshold photothermal retinal lesions are always significant.[11]

Threshold photothermal retinal lesions do not cause the complications associated with suprathreshold lesions and thus do not require medical treatment exceeding limited first responder care to prevent any complications that could lead to a disabling outcome.

Subthreshold photothermal retina lesions have not been shown to result in permanently disabling loss of visual acuity or visual field impairment. Therefore, subthreshold photothermal retinal lesions are not significant.

Location

When located on the periphery of the retina, threshold lesions may not even be noticed by the person who has them and can have negligible effects on the person's visual acuity or field of view. However, threshold lesions on the macula can cause loss in visual acuity in addition to the impairment in central visual field of view. In the absence of specific data sets that would clarify the likelihood of this occurrence, a threshold photothermal retinal lesion on the macula is considered significant (see Figure 1 below). A single or even a few threshold lesions on one or both eyes is not likely capable of causing a single scotoma with a 25% or more loss in the visual field. It is also unlikely that a single or even a few threshold lesions on one or both eyes could result in a person's visual field being reduced to 60° or less.[12] Therefore in practice, only centrally located threshold lesions need to be considered for significance.

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[11] I.e., we assume that $P(SI|IO) = 1$ when the injury is a suprathreshold photothermal retinal lesion. If, at a later time, a relevant and definitive data set is identified that can refine the $P(SI|IO)$ (given only limited first responder level of medical treatment) to value less than 1, then this RSI Implementation Guidance will be updated.

[12] Although technically possible, it is highly unlikely for an exposure to cause multiple threshold lesions (without any of these lesions being centrally located or suprathreshold) such that they collectively add up to a scotoma causing 25% loss in field of vision. Same is true for multiple threshold lesions resulting in a visual field 60° or less especially given the fact that binocular vision allow for some level of visual compensation. Given the scenario and

$$P(SI|IO)_{Subthreshold} = 0\%$$

$$P(SI|IO)_{Suprathreshold} = 100\%$$

$$P(SI|IO)_{Threshold\ not\ on\ Macula} = 0\%$$

$$P(SI|IO)_{Threshold\ on\ Macula} = 100\%$$

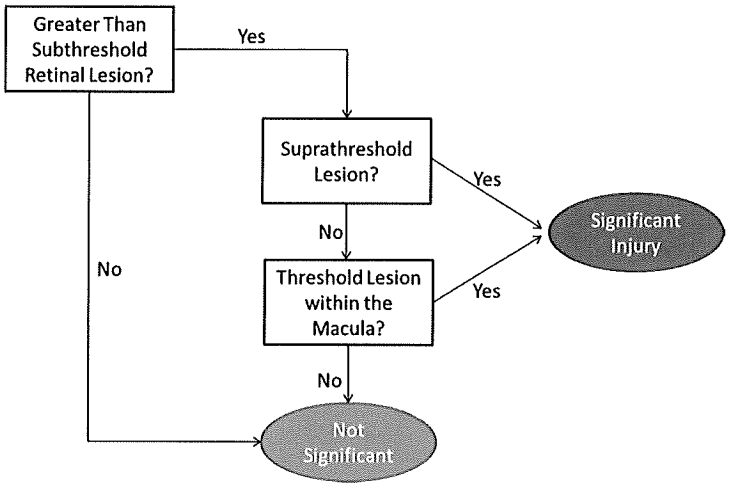

Figure 1: *(left)* Assumed values of the conditional probability "signficant given injury occured" for four injuries (see Eq.1). *(right)* Decision diagram for deteriming the significance of an injury for photothermal retinal lesions.

Probability of Injury Occurrence, P(IO), and Estimating RSI

As shown in Eq.1, the risk of significant injury depends on both the likelihood that the injury occurs and the likelihood that an injury is significant given it occurred, i.e. the injury is permanently disabling. As stated in Figure 1, the P(SI|IO) for suprathreshold lesions and threshold lesions on the macula is 100%. To estimate the RSI for a particular NLW system using these definitions and values, one would have to be able to estimate the probability of causing threshold lesions on the macula and suprathreshold lesions anywhere on the retina, i.e. P(IO). In an operational setting, there would be a number of factors that will influence P(IO). For non-lethal dazzling lasers,[13] this would include the expected distribution of engagement ranges, laser power output, pointing accuracy and fire control, ambient lighting conditions, dwell time, incident angle, and the use of aided optics.[14] P(IO) can also be greatly influenced by target behavior as people attempt to avoid, escape, and evade being hit by the laser. These variations would all affect the distribution of expected doses incident on the target population. A model would then be needed to transform this distribution of doses into a distribution of expected injuries, perhaps given biological variation among the target population, and including the size and location of the lesion on the retina.

Of course, the precision required for an estimate of RSI for a given system depends on the particular system and the system's RSI requirement. The definitions of significant retinal lesion injuries above should not be taken to imply that NLW system programs have to specifically assess the risk of injury to

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scope of the analysis here, incident laser energy will likely be a point source and in the visible spectrum. Point sources will minimize the lesion spot size, and visible wavelengths will ensure a blink response that will mitigate retinal injury potential due to longer duration lesion-causing exposures. If aspects of a developmental system or operational scenario makes this a more likely occurrence, then this assumption can be challenged or reassessed for that particular scenario.

[13] Although this example talks about dazzling lasers, the significance of retinal lesion injuries described in this document apply to any non-lethal stimuli that could potentially cause these types of injuries to include the light-emitting diode (LED) devices and broad band light sources including flashbang devices.

[14] This list is not intended to be exhaustive of all the factors that would affect dose distribution.

this level of fidelity, particularly if less intensive estimates can be made and reasonably shown to be more conservative. Dazzling lasers can typically cause compelling warn glare effects or warn and suppress glare effects with laser irradiance[15] values that are above MPE yet well below an irradiance that could cause significant retinal injuries.

Estimating RSI in Practice – Some Illustrative Examples

Suppose a developmental dazzling laser system is intended to cause non-lethal effects with an irradiance value of 250 $\mu W/cm^2$ and an RSI requirement of <1%. To test whether the system meets the RSI requirement, the system developers could develop and run computational retinal injury simulations, or given that the effects in this case are achieved well below the ANSI MPE, they could make a programmatic resource decision to use the ANSI standard as a surrogate for a more in-depth RSI assessment. Since the probability of exceeding MPE is less than the probability of causing a significant retinal injury, a system that has less than a 1% probability of exceeding MPE will certainly meet a less than 1% RSI requirement. The point is not that the system is being designed to a safety rather than a significant injury standard (which is what RSI is), but for convenience, the system developers, program manager (PM), or the test evaluation community can choose to use a more conservative estimation approach. Convenience in this case could mean that using MPE as a surrogate for RSI will cost less and may avoid potential schedule risks, while not having a significant impact on the system design or its ability to be an effective NLW.

If however, the system being developed is intended to, for example, create greater suppressive effects during daylight conditions, and it is determined that the 'MPE-as-surrogate-for-RSI' approach will be too restrictive in system design, then more in-depth estimates in line with the definitions of significant injury above can be pursued. As before, the PM can choose, depending on the assessed cost/risks vs. benefit to the program, to use a model or method that is less conservative than the MPE but more conservative than the set of P(SI|IO) values in Figure 1. For example, the PM may choose to assume, for the RSI analysis, that any threshold retinal lesion, whether on the macula or not, is significant. This would allow the PM to use a simple model based on a dose response curve for threshold lesions instead of having to develop a model and take spatial measurements that would allow for an assessment of lesion location on the retina. Again, if this conservative estimate allows the PM to demonstrate that the RSI requirement was met, while not significantly impacting the design and/or effectiveness of the NLW, then this would be the most efficient course of action.

[15] "Irradiance" is the radiant flux, i.e. the power per unit area incident on or through a surface. Irradiance typically has units of W/m^2 or W/cm^2.